the LTC market, Lilly nearly tripled its LTC sales force to 160. *Id.* Lilly continued to increase the size of its LTC sales force thereafter.

74. Lilly's stated purpose for expanding the LTC division was to, *inter alia*, maximize Zyprexa sales to patients who receive their medications *via* a LTC pharmacy. Indeed, Lilly even disseminated materials to LTC sales representatives overtly referring to the "Golden Opportunity in LTC Care" and the data that supported the vast potential for Zyprexa sales in this off-label market.

75. Lilly maintained a Zyprexa LTC sales division to fulfill one purpose - to aggressively promote Zyprexa on behalf of Lilly to LTC facilities that care exclusively for the elderly, despite the lack of any clinical trials or FDA approval for the use of Zyprexa in the elderly. Plaintiff-Relator gained personal knowledge of these facts during Lilly employment and has evidence substantiating these facts in the Lilly documents she retained from her Lilly employment, some of which are attached hereto as Exhibits. As alleged herein and in the expanded discussion of Lilly and its off-label promotion of Zyprexa in section IX, Lilly trained its LTC sales force to maximize Zyprexa's LTC care revenues.

76. For the duration of her employment with Lilly, Plaintiff-Relator's territory encompassed the LTC market for parts of Northern California, which she covered alone, and the scope of her employment was to promote, market and generate increased revenues from sales of Zyprexa prescriptions written to elderly LTC nursing home residents. Plaintiff-Relator detailed the Stockton Territory within the Sacramento District which encompassed Modesto, Stockton, Lodi, Mantica, Oakdale, Ripon and the surrounding regions.

77. Plaintiff-Relator was required by Lilly to participate in and to graduate from a rigorous 4 week training course at Lilly's corporate headquarters in Indianapolis, Indiana.

78. There were 17 "new hire" LTC sales representative trainees from all over the United States in Plaintiff-Relator's training class. The LTC sales division was uniform throughout the country. All LTC sales representatives received uniform training, they all received the same Zyprexa marketing materials (of course all geared to selling Zyprexa to elderly patients) and all LTC sales representatives market Zyprexa in the LTC demographic in essentially the same manner, no matter which state and which territory.

79. The first two weeks of training focused on Zyprexa. The training topics included an "introduction" to the drug and what it does, the fundamentals about Zyprexa's competitor drugs and training about why Zyprexa is comparatively superior. LTC trainees were also given studies about Zyprexa, Zyprexa's competitors, Zyprexa's effectiveness compared to placebo and/or other atypicals and other similar studies that trainees were required to memorize. The purpose of memorizing these studies was for the Lilly LTC trainees to cite to and explain in detail these Zyprexa-supporting studies during sales calls on LTC physicians. Plaintiff-Relator was given Lilly training materials in connection with her training and was continuously tested throughout her training to monitor her progress.

80. The second two weeks of the training period focused entirely on how to sell Zyprexa to elderly patients in LTC skilled nursing facilities. In reality, this aspect of Lilly's training was a study in how to successfully market Zyprexa and induce physicians

to prescribe Zyprexa to elderly patients to treat symptoms such as agitation, irritability, dementia and the like, all of which constitutes illegal off-label marketing.

81. Among other things, Plaintiff-Relator received extensive training from Lilly corporate training officials on subjects such as how to talk about the drug's efficacy in the treatment of Alzheimer's patients, how to induce physicians to ask "unsolicited" questions about Zyprexa off-label uses and to focus the marketing message on symptoms and behaviors and Zyprexa's superior efficacy in "Restoring Calm," and that "nothing calms like Zyprexa." The sales materials discussed below carry forward this "Calming" selling message.

82. Lilly reinforced this training by providing mandatory role playing sessions designed to replicate what the LTC sales person would experience in the field when calling on LTC physicians.

83. Among other things, Lilly LTC salespersons including Plaintiff-Relator, engaged in role playing exercises that emulated physician sales calls. Lilly made it a prerequisite to "graduation" from Lilly's initial rigorous 4 month training for each LTC sales representative to receive a passing grade on a *videotaped* role-playing session designed to simulate "real life" marketing calls with LTC physicians.

84. Since Zyprexa has not been approved by the FDA to treat the elderly, Lilly trained its LTC sales persons (through such exercises as role playing) to discuss Zyprexa's efficacy and safety in treating generic symptoms known by Lilly to be commonplace in elderly LTC patients. The primary symptoms LTC sales representatives were trained to focus on were hostility and aggression, and to highlight Zyprexa as the drug of choice to "restore calm" in such agitated patients.

85. Notably, Plaintiff-Relator received scant training on schizophrenia and bi-polar disorders during the four weeks if her comprehensive LTC sales training. Instead, the majority of the training involved geriatric data and information. Lilly's focus on geriatrics over Zyprexa's indicated uses evidences Lilly's illegitimate purpose in maintaining a LTC sales division and reveals its focus and intent to achieve blockbuster off-label sales of Zyprexa. The calculated sales and marketing tactics demonstrate Lilly's conscious aforethought to off-label marketing.

86. Plaintiff-Relator, having worked in the pharmaceutical sales prior to Lilly, vocally questioned her Lilly trainers about the legality of the marketing practices being taught, specifically, she questioned the off-label nature of the Zyprexa marketing campaign promoting Zyprexa's safety and superior efficacy for geriatrics to LTC physicians, nursing home employees and LTC pharmacies. Plaintiff-Relator was assured that by following Lilly's training on how to deliver the LTC Zyprexa message, off-label regulations would not be violated.

87. The role-playing seminars were not limited to LTC training. Rather, mandatory role-playing occurred at every Lilly sales meeting so sales representatives could "brush up" and hone their skills in delivering the misleading, deceptive and illegal Zyprexa off-label marketing tactics.

88. In addition to communicating such practices during frequent regional and district sales conferences, Lilly engrained its off-label marketing message during once or twice annual national sales meetings. During national sales meetings, specific gatherings, seminars, and training sessions were held solely for the Lilly LTC sales representatives.

89. As is detailed below, once Plaintiff-Relator graduated from training, she was continuously given Zyprexa marketing materials, such as studies, LTC implementation guides and "detail aids" tailored to selling Zyprexa in the geriatric market. Lilly's Zyprexa sales materials were the creation of the Zyprexa Brand Team, the division within Lilly responsible for developing the marketing and promotional selling message for Zyprexa in the United States.

90. Plaintiff-Relator also occasionally received promotional materials distributed by her Lilly manager, Dan Tubridy ("Tubridy"). One egregious example of such materials was a one-page sheet containing 2 form letters (one for Zyprexa and one for Zyprexa Zydis) with "fill in the blanks" to personalize the message to client-target physician and his or her geriatric patients Zyprexa doses and times of administration. See Exhibit "B." The letter's purpose was to suggest to the physician that his or her patients' Zyprexa dosage should be increased to reduce "nursing time and effort." Tubridy instructed Plaintiff-Relator to pass out this form letter to her target-physicians to induce an increase in Zyprexa dosage, which translated directly to increased Zyprexa sales revenues, by promoting Zyprexa's known side effect of somnolence. Promotion of Zyprexa as a chemical restraint for difficult, agitated elderly patients was not only illegal unsolicited off-label marketing, but also a wanton derogation of patients' fundamental human rights.

91. Lilly's myopic focus and goal of driving Zyprexa off-label sales is evidenced by the convoluted manner in which LTC sales representatives' performance was evaluated. Job performance hinged entirely upon each LTC representatives *total sales revenues* generated by LTC Zyprexa purchases in her Northern California territory.

Lilly's tunnel vision focus on salespersons profits, rather than number of prescriptions written evidences the avaricious nature of Lilly's illegal marketing pursuit, as it shows salespersons were expected not only to increase market share, but to increase dosages and/or frequency to rive up profits.

92. Plaintiff-Relator was continuously employed as a Lilly LTC sales representative for three years until on or about June 2003. At that time, she voluntarily resigned from her employment to accept a higher-paying pharmaceutical sales representative position with another pharmaceutical company. Plaintiff-Relator began pursing a career change while still a Lilly employee after Lilly executives rebuffed her attempts to rectify the unethical and illegal Zyprexa sales practices implemented and mandated by her Lilly Supervisor, Dan Tubridy.

93. Indeed, prior to leaving Lilly's employ, Plaintiff-Relator submitted to Lilly corporate a 3 page summary documenting all of Tubridy's illegal and unethical conduct. Exhibit "C." Lilly's rebuffed Plaintiff-Relator's attempt to right the wrongs of her manager, simply giving Tubridy a meaningless "warning," which was tantamount to a corporate endorsement of Tubridy's illegal, but successful Zyprexa sales methods. Soon thereafter, Plaintiff-Relator began seeking employment with another pharmaceutical company.

IX. ADDITIONAL FACTUAL BASIS OF LILLY'S ILLEGAL OFF-LABEL MARKETING OF ZYPREXA FOR ELDERLY OFF-LABEL USES AND TO PRIMARY CARE PHYSICIANS FOR OFF-LABEL USE TO TREAT NON-SCHIZOPHRENIC OR BIPOLAR ADULTS.

94. As alleged supra in § VII B, Zyprexa is indicated to treat an exceptionally small subset of the United States population. Indeed, less than 7% of the United States' adult population has been diagnosed with one of the rare mental illness for which

Zyprexa is indicated for the treatment of symptoms relating thereto – schizophrenia and bipolar disorder.

95. It is not by stroke of luck that Zyprexa has been Lilly's largest selling drug for a number of years and has generated astounding blockbuster revenues for the drug company. For years, Zyprexa generated several billions of dollars of revenue for the company and was among the top ten best selling drugs in the world. In 2003, Zyprexa sales rose to $4.4 billion and assumed the rank of world's fifth best selling drug.

96. Rather, from the outset, Lilly recognized the promotion of Zyprexa's not medically accepted indications and not medically necessary uses as the key to Zyprexa's blockbuster success, i.e., promoting the use of Zyprexa to treat off-label demographics who present with symptoms akin to those exhibited by patients diagnosed with those exceedingly rare mental illnesses – depression, sleeplessness, agitation: 1) elderly LTC residents, 2) depressed and distracted adults who are not diagnosed with schizophrenia or bipolar disorder and 3) children with conditions such as ADHD, autism, mood disorders and disruptive children. Lilly devised this game plan despite its awareness of numerous serious treatment emergent side effects caused by Zyprexa including diabetes, hyperglycemia, extraordinary weight gain and metabolic syndrome, to name a few.

97. Indeed, Lilly funded calculated studies with methodologies intended to contrive positive clinical data about Zyprexa to ensure Zyprexa's numerous, dangerous and even deadly side effects were kept from public purview.

98. Lilly succeeded. Zyprexa's incredible revenues and sales ranking directly stems from the drug's dangerous overuse off-label that have not been found by the FDA

or medical compendia to be safe or effective. This dangerous overuse is directly attributable to Lilly's illegal off-label promotional tactics.

99. Upon information and belief, based upon the foregoing, Lilly began planning its national, aggressive off-label marketing campaign for Zyprexa even before Zyprexa had received FDA approval. In this regard, Lilly's devised a strategy prior to Zyprexa's launch to market the drug not only for use with elderly and children, but also for a constellation of broad symptoms in the broad realm of mood and thought disorders, a strategy that gave rise to an ongoing pattern of false and misleading conduct.

100. This conduct directly and proximately resulted in both the submissions of claims for not medically accepted indications and not medically necessary uses of Zyprexa to Medicaid, Medicare, VA and CHAMPUS/Tricare programs throughout the country as well as adverse health effects among participants of those programs.

101. Through this planning Lilly funded clinical studies for Zyprexa, for on and off-label uses, which ultimately Lilly planned to be used by its sales representatives to promote Zyprexa. Indeed, Plaintiff-Relator was given such studies by Lilly with the expectation that she learn the details of the studies backwards and forwards and use the contrived results of the studies in promoting Zyprexa off-label.

102. Lilly furthered its illegal avaricious Zyprexa business plan by creating a deceptive and misleading marketing campaign to create a LTC market for Zyprexa, among other off-label markets. Lilly falsely touted Zyprexa's superior efficacy in treating the generic mood and behavioral symptoms of schizophrenia and bipolar disorder; symptoms that Lilly knew were also prolific in the elderly population.

103. The purpose of the deceptive scheme was to create the misimpression that geriatric patients presenting with a myriad of symptoms that did not fit into a precise diagnostic category were Zyprexa candidates, thereby creating a broad, ill-defined market for Zyprexa in the elderly demographic.

104. Lilly tweaked the message slightly for its other sales divisions, such as its primary care physician sales force, to achieve the same impact - to create the misimpression that adult and pediatric patients presenting with a myriad of symptoms that did not fit into a precise diagnostic category would benefit from being prescribed Zyprexa in increasing doses, thereby creating an across the board off-label for Zyprexa among patients who relied upon Medicaid, Medicare, the VA and/or CHAMPUS/Tricare to fund their necessary prescription drug needs.

A. Lilly's Calculated Training Of Zyprexa Sales Representatives to Successfully Market Zyprexa Off-Label to, *inter alia*, Medicaid/Medicare Beneficiaries

105. Lilly's scheme was highly successful. Data shows that well over half of all dollars spent on Zyprexa is spent on non-medically accepted or not medically necessary uses. Moreover, Zyprexa has been prescribed to more than 12 million people worldwide since the atypical antipsychotic's launch in 1996. Crucial to this Blockbuster success was Lilly's aggressive marketing of Zyprexa for elderly use through its LTC sales division, which consisted chiefly of exaggerating the drug's uses, while concealing its life-threatening side effects.

106. Lilly created complicated marketing structures that appeared independent from their proprietary of promotion forces.

107. Lilly sales representatives were expected in the course and scope of their employment to identify specific doctors (*i.e.* physicians who were already prescribing large volumes of Zyprexa or physicians whose antipsychotic "business" Lilly wanted to obtain) to recruit and communicate Lilly's interest in funding research opportunities and clinical trials at their institutions. Doctors who were willing to speak favorably about Zyprexa often were given substantial funds by Lilly in the form of research grants, many unrestricted. These funds were in reality kickback paid to induce the physicians' use of Zyprexa.

108. Lilly engaged in this duplicitous conduct to create the false perception that respected physicians were using and investigating Zyprexa's efficacy in non-medically accepted and not medically necessary uses on their own initiative, and not as a result of Lilly's marketing activities. And in addition to providing free travel to resorts, free lodging and free meals, Lilly also paid these physicians to give talk segment medical education seminars, advisory boards, consultants meetings, speakers bureaus and similar events that favorably discussed not medically accepted and not medically necessary uses of Zyprexa.

1. Promotion to the Elderly

109. The generic symptoms Lilly unlawfully promoted Zyprexa to treat mimicked those of dementia and/or Alzheimer's, including agitation, anxiety, and insomnia. By marketing the drug for the treatment of ***symptoms*** for which Zyprexa was not approved, Lilly violated strict FDA labeling regulations detailed *infra*.

110. Lilly encouraged use of Zyprexa in the elderly demographic to treat multiple symptoms that might be categorized as relating to dementia and/or Alzheimer's.

To assist in these efforts, Lilly created patient profile detail aids whose focus was on "behavior treatment" such as agitation, suspiciousness, depressive mood, anxiety, and lack of concentration. By focusing on symptoms rather than the diagnoses of schizophrenia or bi-polar disorder, Lilly intended to overcome Zyprexa's lack of any FDA approved market for Zyprexa in the LTC demographic.

111. Lilly propagated the intentionally misleading message that Zyprexa was indicated for the treatment of dementia by directing its sales force to focus on behavioral and cognitive symptoms such as anxiety, depression, agitation during physician sales calls.

112. Among the most common, treatment-emergent adverse ***side effects*** of Zyprexa and the other atypical antipsychotics is ***somnolence***. Somnolence is defined as sleepiness, the state of feeling drowsy, ready to fall asleep. Within its drug class, Zyprexa is the most heavily sedating.

113. One approach Lilly devised for its LTC sales representatives was to market Zyprexa's somnolence side effects as method to reduce patient care hours by essentially chemically restraining demanding elderly patients.

114. Indeed, Lilly preyed upon the fact that providing care to elderly LTC residents who typically exhibit combative behavior and aggression is considerably stressful, frustrating and time consuming.

115. By way of example, Plaintiff-Relator and other Lilly LTC sales representatives were given studies by Lilly to distribute to LTC staff espousing ostensibly clinical evidence that elderly patients prescribed Zyprexa required fewer skilled nursing staff hours than patients prescribed other competing medications. One such study was

Olanzapine Treatment of Psychotic and Behavioral Symptoms in Patients With Alzheimer Disease in Nursing Care Facilities, *Archives of General Psychiatry*, Vol. 57, pg. 968 (Oct. 2000) See Exhibit "N." Plaintiff-Relator and other Lilly LTC sales representatives were told to point directly to pg. 971 of this study and read:

> "A statistically significant reduction in caregiver distress, measured by the sum of the Occupational Disruptiveness scores for Agitation/Aggression, Hallucinations, and Delusions (Core Disruptiveness) was seen for patients treated with 5 mg/d of olanzapine... Caregivers of patients treated with 5 mg/d of olanzapine also had similar reductions in Occupational Disruptiveness associated with Anxiety, Appetite and Eating Disorders, Delusions, Depression/Dysphoria, and Hallucinations items."

116. Lilly LTC sales representatives were taught to create "action" in nursing homes by marketing Zyprexa's "calming" effect. In truth, this was Lilly's thinly-veiled marketing of Zyprexa as an effective **chemical restraint** for demanding, vulnerable, and needy patients.

117. In addition, Plaintiff-Relator's manager disseminated a form letter to the representatives under his supervision and control that touted Zyprexa as providing superior efficacy and safety when compared to placebo and significantly reduced caregiver burden at a dose of 5 mgs daily. See Exhibit "B." This statement was "supported" by a footnote citing a study that ostensibly supported this mendacious marketing of Zyprexa as a chemical restraint. *Id.*

118. The form letter also expressed the medical opinion that the 5mg dose of Zyprexa should be administered at 5 pm. *Id.* This was a Lilly-trained "5 at 5" slogan which translated essentially referred to give your patients 5mg of Zyprexa at 5pm and they will sleep through the night eliminating the disruptive late night conduct demanding of caregiver time.

119. Atypical antipsychotics are powerful medications, laden with serious treatment-emergent side effects. Zyprexa is a dangerous drug even when prescribed for on-label use. It is even more dangerous for the elderly. Zyprexa and the other atypical antipsychotics have not received FDA-approval to treat the elderly because of atypicals' serious risk of harm and the lack of scientific evidence of its safety and efficacy in this population.

120. On April 11, 2005, the FDA issued a public health advisory to alert health care providers, patients, and patient caregivers of its determination based upon clinical studies that using Zyprexa or the other atypicals to treat behavioral disorders in elderly patients with dementia is associated with increased mortality. The FDA's examination of the specific causes of these deaths revealed that most were either due to heart related events (e.g., heart failure, sudden death) or infections (mostly pneumonia).

121. Accordingly, the FDA required Lilly to amend Zyprexa's label to include a "black box warning" of this deadly side effect. A 'black box' designation is an FDA-recommended/mandated warning based upon clinical research studies, for certain drugs that may cause serious and potentially life-threatening side effects. The FDA requires that a black box warning be placed on the labeling or literature of a prescription drug, or in literature describing it. It is the strongest warning the FDA requires.

122. Because of Lilly's promotion of Zyprexa's somnolence side effect as an attribute of the drug, patients were intentionally medicated with incapacitating antipsychotic agents such as Zyprexa to control patient behavior, "restore calm" and reduce the time needed to be spent to treat patients, especially the those patients who

required burdensome, time intensive care, as well as those patients who demonstrated "oppositional" and "defiant" behavior.

123. The use of atypical and typical antipsychotic drugs to control the behavior of elderly nursing home residents who are not psychotic constitutes an **unlawful chemical restraint**. Lilly's unlawful and unethical promotion of the use Zyprexa, off-label, as a **chemical restraint** resulted in patients being restrained in a zombie-like state, unable to complain or object. Prescriptions were medically unnecessary

124. Government healthcare programs would not have paid prescription drug reimbursement claims caused to be submitted by Lilly's mendacious and unlawful marketing of Zyprexa's somnolence side effect had it known the truth.

125. As part of the Zyprexa sales campaign, Lilly disseminated Zyprexa LTC Implementation Guides to its LTC sales representatives. Lilly created a LTC Implementation guide specifically to roll out each new year's version of Lilly's LTC patient profile.

126. Lilly's LTC detail aid was a LTC stereotypical patient - an elderly patient representing the agitated, hostile geriatric patients LTC physicians treat everyday. "Rose" was the detail piece used by LTC sales representatives to represent the angry and hostile elderly patient complaining of symptoms such as anxiousness, irritability, mood swings, and disturbed sleep. See eg Exhibit "D."

127. The "Rose Jackson" ("Rose") detail aid contained only conspicuously printed wording like "Agitation," "Depressive Symptoms," "Aggression," Irritability," and "Sleeplessness" calculated to imply that Zyprexa was indicated for the treatment of such **symptoms**. *Id.* The top of the front page conveyed the message "Helping you bring dignity

to patients' lives." *Id.* Nowhere on this Rose detail aid did Lilly explicitly disclose that Zyprexa's FDA-approval was limited to the treatment symptoms of schizophrenia and bipolar mania and not the other generic symptoms highlighted in print on the detail aid (ie sleeplessness, irritability, depressive symptoms). *Id.*

128. The detail piece featured a large color picture of "Rose," an elderly woman composed to appear agitated and combative. *Id.* Lilly's strategy goal for the Rose detail piece was to "encourage doctors to try Zyprexa in patients similar to the one we profile, Rose Jackson. In this way, doctors can see for themselves that Zyprexa **stabilizes symptoms and behaviors safely.**"

129. "Rose" was designed to personalize the sales representative's promotion of Zyprexa as the wonder drug to "calm" difficult patients and to reduce patient treatment time. Plaintiff-Relator was instructed to show this image to clients to reinforce the marketing message that Zyprexa can treat his or her angry, agitated and difficult patients.

130. Lilly even disseminated along with the Rose detail aid the marketing message the sales representative was expected to learn verbatim and then deliver during LTC physician sales calls, which Plaintiff-Relator still recalls to this day. Lilly trained its sales representatives to show the Rose detail aid to physicians and deliver a verbatim sales pitch probe recommending that the physician's patients like Rose are indicated for treatment with Zyprexa and would benefit from commencing a Zyprexa regimen. By way of example, Plaintiff-Relator and other sales representatives would ask leading questions to physicians relayed in the LTC Implementation Guide, such as, "Doctor, does it make sense to use Zyprexa as a first choice for a patient like Rose, since Zyprexa helps to safely stabilize

symptoms and behaviors such as agitation, anxiety, hostility, delusions, and resistance to care?" See Exhibit "E."

131. Future iterations of the Zyprexa LTC Implementation Guides similarly helped deliver the message that Zyprexa should be prescribed to treat moods, behaviors and symptoms. By way of example, in the January 2003 "Rose" Detail Aid, Lilly describes to sales representatives, including Plaintiff-Relator, that on the detail aid's cover, "there is also the addition of a couple more mood symptoms, which is to emphasize our unique ability in treating mood." See Exhibit "F."

132. When detailing the Zyprexa 2003 LTC Rose detail piece, sales representatives, including Plaintiff-Relator, were instructed to deliver the message that, "Because Zyprexa treats both symptoms of elevated mood and psychosis, it helps you restore calm to the resident, the staff and even the other residents- the environment will be less disruptive since the resident will be calm instead of yelling, 'Help me-help me.'"

133. Further, on the cover of later versions of the Zyprexa LTC Rose detail piece, along with the symptoms and behaviors, Lilly finally incorporated the language, "ZYPREXA is indicated for the treatment of" and then lists the two approved indications for use for Zyprexa, schizophrenia and acute bipolar mania. Exhibit "G."

134. Among the other duplicitous sales tactics implemented by Lilly at the corporate level involved serious violations of the confidentiality of protected health information safeguarded by the HIPAA regulations as well as breaches of the doctor-patient privilege.

135. Although Lilly LTC salespersons were evaluated on total Zyprexa sales revenues rendering prescribing physicians, the LTC pharmacies, Lilly LTC sales

representatives' relationships with LTC pharmacies were nonetheless pivotal in successfully promoting Zyprexa within the LTC context.

136. Indeed, LTC pharmacies arrange for and bill the government plaintiffs' for the drugs prescribed by physicians to LTC facility residents. LTC pharmacies are known as 'closed-door' pharmacies. Closed-door pharmacies are full-service pharmacies, but which exclusively provide prescription drug delivery services to residents of LTC facilities.

137. LTC pharmacies regularly bill Government-funded healthcare plans such as Medicaid for medications prescribed by medical professionals working onsite at the nursing homes.

138. When a patient in a nursing home requires a prescription medication, physicians give written or verbal prescription orders for their patients to nurses. The nurses transmit the prescription orders verbally or by facsimile to the responsible LTC pharmacy clerical data entry personnel to be entered into the LTC pharmacy's computerized order entry system.

139. Once a physician's prescription order is processed in the LTC pharmacy's order entry system, a pharmacist fills the prescription based on the physician's request and the medication is then shipped to LTC skilled nursing home facility where the patient resides.

140. Once the LTC has filled and shipped a prescription, the LTC pharmacy prepares a claim for submission to the Government seeking reimbursement for the cost of the prescription drug.

141. Lilly knew that the vast majority of elderly LTC residents rely upon, *inter alia*, Medicare and Medicaid to fund in whole or in part their prescription drug costs.

142. Since LTC pharmacies play an integral role in the delivery of prescription drugs to LTC residents, LTC pharmacies were also "clients" of LTC sales representatives which were targeted for Zyprexa off-label marketing, albeit less frequently than the physicians who are writing the prescriptions.

143. To identify and target the most influential doctors, Lilly encouraged LTC representatives to develop personal relationships with the LTC pharmacies to gain access to the pharmacies' local prescribing data.

144. In addition, LTC pharmacies provide consultant pharmacist services to the LTC facilities they service. Such consultant pharmacists work closely with physicians writing orders in LTC facilities to purported "educate" LTC physicians about prescription alternatives.

145. Because of the significant influence LTC pharmacies play in the prescribing decisions of LTC physicians, Plaintiff-Relator made once monthly sales calls to LTC pharmacies in her territory to ensure the pharmacies encouraged the use of Zyprexa in the facilities they service. Plaintiff-Relator specifically recalls making sales calls to LTC pharmacies to combat financially-incentivizing rebate agreements the LTC pharmacies had negotiated with Janssen, the manufacturer of Zyprexa's competitor Risperdal. Such rebate agreements made it *profitable* for the LTC pharmacy to use its consulting pharmacists power and influence to push LTC physicians to use Risperdal over Zyprexa.

146. Plaintiff-Relator and the LTC sales division generally were also instructed and trained on how to obtain Drug Utilization reports, also known by the acronym "DURs," from the LTC skilled nursing home executive staff. See Exhibit "G."

147. A "Drug Utilization Report" is a report delineating protected health information detailing which patients were taking which drugs and which physician was prescribing those drugs.

148. Lilly enforced this directive by tracking LTC sales representatives' success rates in obtaining the coveted DUR reports. See eg Exhibit "H."

149. To keep the LTC sales representatives across the nation abreast of Zyprexa LTC sales as well as successful LTC promotional tactics, Lilly disseminated a LTC Best Practices Newsletter 4 times a year. *Id.*

150. The LTC Best Practices Newsletter is packed with evidence and admissions of Lilly's unlawful LTC off-label marketing campaign. *Id.* It openly addresses Lilly's improper expectation that Lilly LTC sales representatives gain access to protected confidential patient information (i.e. DURs), instructs the sales representative to do rounds with the "NH [nursing home] prescriber" – a highly offensive invasion upon the doctor patient privilege, and contains messages from Lilly executives such as Grady Grant and Tom Olinski, Lilly National Sales Directors and Mike Murray – the LTC Western Division Sales Director and identifies LTC top sales performers across the nation to "SELL ZYPREXA!" The Newsletter also features a "Coaches Corner," which provides tips on maximizing LTC sales of Zyprexa. In the 2003 Winter edition of the Newsletter, the Coaches Corner featured an article by "Wayne Mielke, [the] "Long Term Care Coaching Champ of 2001, on the importance of **DUR ATTAINMENT**." *Id.*

151. Plaintiff-Relator received the quarterly Lilly LTC Best Practices Newsletter in the course and scope of her Lilly employment.

152. Lilly paid honoraria or speaker fees as part of their overall off label Zyprexa marketing scheme. The payment of and acceptance of the financial incentives in exchange for prescriptions violated the federal Anti-Kickback Statute. See § XI.

153. Lilly management approved huge speaker fee budgets as a means to disguise large payments to physicians who were willing to prescribe Zyprexa off label. Lilly established large budgets for each LTC representative to induce physicians to write off label. The speaking fees were typically $1500 for a "lunch and learn."

154. One method employed by Lilly to conceal kickback payments under the guise of legitimacy was the creation of a "speaker" program. Lilly even established an annual budget for LTC sales representatives to "invest" in speaker fees/honoraria as well as an annual entertainment budget to impress and attract physicians' business.

155. Physicians were even "groomed" by Lilly to be speakers by attending all-expense paid speaking seminars in resort-like atmospheres. These seminars were in truth designed to market Zyprexa, not to provide speaker training. For large volume prescribers, regardless of whether they exhibited a shred of public speaking acumen, after the seminar such physicians were retained and paid handsomely to speak about Zyprexa.

156. The speaking engagements were frequently a mere sham, indeed, Plaintiff-Relator has personal knowledge that such Lilly-paid speakers were even paid to give pointless presentations to their colleagues at the healthcare facility with which they were affiliated.

157. Such thinly-veiled kickback payments were made with the intent that in return, the paid physician would prescribe Zyprexa for symptoms and illnesses that were unrelated to schizophrenia and bipolar disorder to the frail elderly population. Lilly LTC

sales representatives used their improper access to DURs to identify physicians to solicit to enter into unlawful financial relationships.

158. Plaintiff-Relator has personal knowledge that Lilly established similar illegal referral relationships with health care providers throughout the United States.

159. Sales representatives, including Plaintiff-Relator, were instructed by Lilly on implementing "Peer-to-Peer Programs" intended on having paid physicians lecture on designated topics, including off-label topics. Typically, sales representatives, including Plaintiff-Relator, would organize continuing medical education ("CME") programs and offer these programs to their physician customers.

160. By way of example, one such program was "FDA Regulated Programs (Promotional)" wherein the sales representative selects a program topic and a physician under contract with Lilly Lecture Bureau. If the chosen speaker is not under contract, he or she must sign a contract to speak about Lilly's products. See Exhibit "I." The Sales representative submits a speaker payment request to Lilly's Lecture Bureau.

161. To complete the payment process to physicians, Plaintiff-Relator would contact the Lilly Lecture Bureau and the Lilly Lecture Bureau arranged for the check to be sent, typically directly to the lecturing physician. See Exhibit "J."

162. Lilly's Peer to Peer Programs Implementation Guides stresses that the "program time should be balances equally with entertainment time." See Exhibit "K." Further, the sales representative was instructed to pre-set menus and "pre-select wine list and order group appetizers." *Id.*

163. Another example of a Lilly Peer to Peer Program is the Independent Scientific Exchange (Non promotional Program). This program is ostensibly initiated by the